

Application No. 10/597,636  
AMENDMENT dated November 3, 2011  
Reply to Office Action of August 25, 2011  
Attorney Docket 9248-88834-US

#### REMARKS

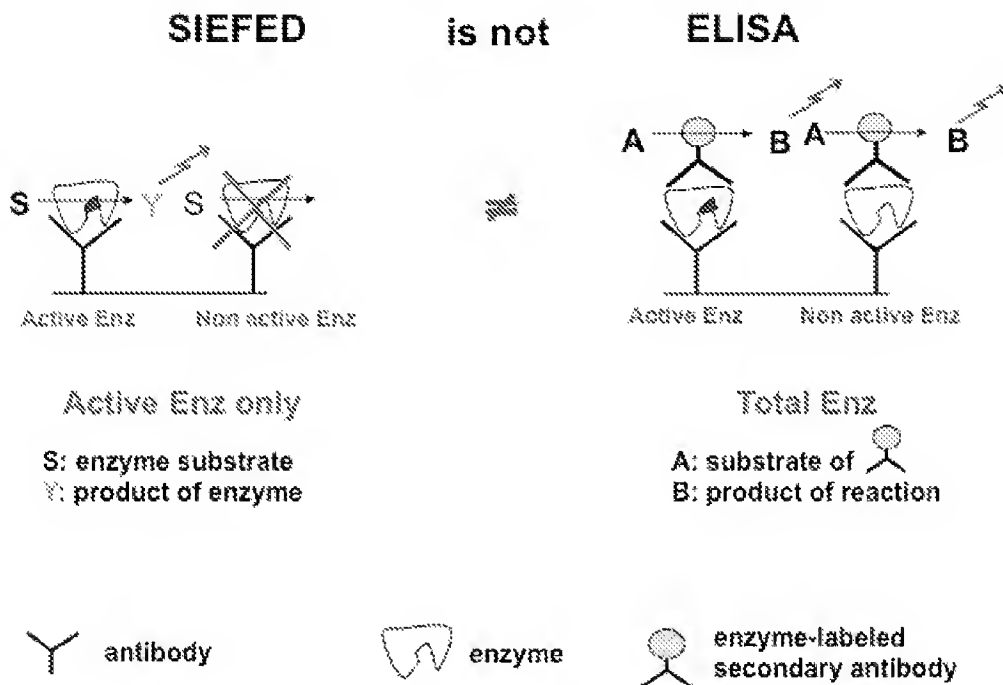
Claims 15, 17-23, 26, 32, 34-37, 39, and 40 are rejected. Claims 1-14, 16, 25, 33, and 38 were previously canceled while claims 24 and 27-31 were previously withdrawn. Claims 15 and 26 have been amended herein. Therefore, claims 15, 17-23, 26-32, 34-37, 39, and 40 are pending and at issue. Applicants respectfully request reconsideration of the rejections and allowance in light of the foregoing amendments and the following remarks herein.

As an initial matter, Applicants would like to thank the Examiner for withdrawing many of the rejections stated in the previous Action. Applicants note, however, that the currently cited references are also readily distinguishable for many of the same reasons discussed in the previous response. Applicants believe a brief summary of the present application and the currently cited references may help the Examiner understand the significant fundamental differences between the present claims and the cited art.

#### *The Present Application*

As previously discussed, the present application is generally directed to a Specific Immunological Extraction Follow by Enzymatic Detection (SIEFED) method and kit. SIEFED measures the enzymatic activity, such as the activity of myeloperoxidase. SIEFED methods and kits are readily distinguishable from other forms, such as Enzyme Linked Immunosorbent Assays (ELISA). ELISA, unlike SIEFED, measures the total amount of the enzyme, including active and non-active, whereas SIEFED only measures active enzymes. This difference should be easily understood in the below drawing.

## Methods



In fact, Applicants have amended independent claims 15 and 26 to more clearly recite that it is the enzymatic activity that is being measured when the enzyme is bound to an immobilized antibody. More specifically, the claims recite immunocapturing the enzyme released by the neutrophil cells and then detecting and/or measuring the activity of the immunocaptured enzyme present which indicates the activation status of the neutrophil cells.

### *The Cited Art*

The cited art, on the other hand, is directed to entirely different methods and kits than the methods and kits recited in the present claims. As mentioned above, an ELISA measures the total amount of the protein, such as myeloperoxidase. In fact, Deby et al. is directed to just such an ELISA. For example, as described in the previous response, Deby et al. is directed to

detection of myeloperoxidase, not to the measurement of its enzymatic activity. For example, Deby et al. describes at col. 21, lines 37-64 that alkaline phosphatase activity is measured which reflects the total MPO and not the active MPO. Moreover, it is the alkaline phosphatase activity which is measured, not the activity of the bound MPO, such as in the present application.

Uchida et al. is directed to a similar method which measures the amount of protein, such as myeloperoxidase, which is then considered to indicate inflammatory gastrointestinal tract disorders. Just as with Deby et al., Uchida et al. is directed to determining the amount of protein and not the activity of immunocaptured enzyme. Therefore, both Deby et al. and Uchida et al. are directed to entirely different methods and kits than those described in the present application.

#### ***Claim Rejections – 35 U.S.C. § 102***

Claims 15, 17-21, 26, 32, 34, 36, 37, and 39 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Uchida et al. U.S. Patent No. 5,552,292 (“Uchida et al.”). This rejection should be withdrawn as Uchida et al. fails to disclose or suggest one or more features recited in the claims.

As noted above, the present claims are directed to SIEFED methods and kits which measure the activity of the immunocaptured enzyme. Uchida et al. fails to disclose or suggest measuring enzyme activity, but instead measures the amount of protein. These are two completely different measurements. The Office Action alleges that Uchida et al. discloses measuring the amount of immunocaptured enzyme released by the neutrophils cells. However, the portions of Uchida et al. cited by the Office Action do not support the allegations. Instead, the cited sections clearly indicate that the method and kit uses ELISA, which measures the total amount of myeloperoxidase, and not the enzyme activity as recited in the present claims. At no point does Uchida et al. disclose or suggest measuring the enzyme activity as recited in the present claims.

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The Office Action also alleges that the enzymes released by the neutrophils include active oxygen species produced and released by the activated neutrophils including myeloperoxidase. However, the active oxygen species are not enzymes. Moreover, Uchida et al. admits that the amount of myeloperoxidase is “determined by a per se conventional immunoassay technique.” Col. 2, lines 16-17. Such a technique is described above as an ELISA that measures the amount of the myeloperoxidase and not the enzyme activity. See, for example, Uchida et al. at col. 4, lines 16-19. Therefore, as Uchida et al. fails to disclose or suggest one or more features recited in the claims, this rejection should be withdrawn and the claims allowed.

*Claim Rejections – 35 U.S.C. § 103*

Claims 23 and 40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Uchida et al. in view of Deby et al. U.S. Patent No. 5,460,961. As noted above, Uchida et al. and Deby et al. are directed to ELISA methods that determine the amount of myeloperoxidase and not the amount of immunocaptured enzyme activity. Therefore, as each of Uchida et al. and Deby et al., when considered alone or in combination, fail to disclose or suggest one or more features recited in the claims, the rejection should be withdrawn and the claims allowed.

Claim 22 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Uchida et al. in view of Deby-Dupont et al., Equine Neutrophil Myeloperoxidase in Plasma: design of a radio-immunoassay and first results in septic pathologies, Veterinary Immunology and Immunopathology 66:257-271 (1998) (“Deby-Dupont et al.”). Further, claim 35 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Uchida et al. in view of Wilson et al. U.S. Patent Application Publication 2006/0257879 (“Wilson et al.”). As noted above, Uchida et al. fails to disclose one or more features recited in the claims. Deby Dupont et al. and Wilson et al. add nothing regarding these deficiencies. Therefore, these rejections should also be withdrawn and the claims allowed.

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The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,  
FITCH, EVEN, TABIN & FLANNERY

Dated: November 3, 2011

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